

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Attorney Docket No. 02-1076-A

TIW

n re the Application of:)
Avella, et al) GROUP ART UNIT: 1653
Serial No: 10/767,516) EXAMINER: UNASSIGNED
Filed: January 29, 2004)
For: Polymerized Hemoglobin Solutions Having Reduced Amounts of Tetramer and Method)))
for Preparing	

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER

In regard to the above identified application:

- 1. We are transmitting herewith the attached:
- 2. a. Form PTO-1449 and 42 cited references;
 - b. Postcard.
- 3. No Fee is required.

4. Please charge any additional fees or credit overpayment to Deposit Account No.13-2490.

Respectfully submitted,

McDONNELL BOEHNEN HULBERT & BERGHOFF LLP

Patrick G. Gattari Reg. No. 39,682

McDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE CHICAGO, ILLINOIS 60606 TELEPHONE (312) 913-0001

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the papers, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this day of Military 2004.

Jill anrang

Sheet 1 of 8

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Patent and Trad		Atty. Docket No.	Serial No.
OIPESO	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		02-1076-A	10/767,516
1	· ,,		Applicant:	
TRANSMENT !		:	Avella, et al	
			Filing Date:	Group:
			January 29, 2004	

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	5,438,041	08/21/95	Zheng, et al			
	5,217,648	06/08/93	Beissinger, et al			
	5,194,590	03/16/93	Sehgal, et al			
	5,061,688	10/29/91	Beissinger, et al			
	5,691,453	11/25/97	Wirtz, et al			
	5,084,558	01/28/92	Rausch, et al			
	5,890,852	11/28/98	Rausch, et al			
	5,955,581	09/21/98	Rausch, et al			
	5,691,452	11/25/97	Gawryl, et al			
	6,150,507	11/21/00	Houtchens, et al			
	5,895,810	04/20/99	Light, et al			
	6,271,351	08/07/01	Gawryl, et al			
	6,288,027	09/11/01	Gawryl, et al			
	4,826,811	05/23/89	Sehgal, et al			
	5,464,814	11/07/95	Sehgal, et al			
	6,498,141	12/24/02	DeWoskin, et al			

EXAMINER	DATE CONSIDERED

Sheet 2 of 8

и	U.S. Department of Commerce Patent and Trademark Office ON DISCLOSURE BY APPLICANT	Atty. Docket No. 02-1076-A	Serial No. 10/767,516
	neets if necessary)	Applicant: Avella, et al	
		Filing Date: January 29, 2004	Group:

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	6,323,320	11/27/01	Sehgal, et al			
	6,552,173	04/22/03	Sehgal, et al			
	5,747,649	05/05/98	Sehgal, et al			-
	6,133,425	10/17/00	Sehgal, et al			
	4,001,401	01/04/97	Sehgal, et al			
	4,861,867	08/29/89	Estep, Timothy N.			
	6,288,027	09/11/01	Gawryl et al.			
	5,206,075	04/27/93	Hodgson Jr.			
	5,929,031	07/27/99	Kerwin, et al.			
	5,278,272	01/11/94	Lai, et al.			
	5,272,236	12/21/93	Lai, et al.		-	
	5,241,031	08/31/93	Mehta, Aspy K.			

EXAMINER	DATE CONSIDERED

Sheet 3 of 8

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office		Serial No.
(1001.202)	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	02-1076-A	10/767,516
	(Use several sheets if necessary)		
		Applicant:	
		Filing Date:	Group:
		January 29, 2004	

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	5,695,840	12/9/97	Mueller, Walter B.			
	6,027,776	02/22/00	Mueller, Walter B.			
	5,296,465	03/22/94	Rausch, et al.			
	6,076,457	06/20/00	Vallot, Bernard			
	5,988,422	11/23/99	Vallot, Bernard			
	5,998,361	12/07/99	Bucci, et al			
	5,789,376	08/04/98	Hsia			
	5,380,824	01/10/95	Marschall, et al			
	4,049,673	09/20/97	Scheinberg		1	
	4,485,174	11/27/84	Chaing, et al			
	4,053,590	10/11/97	Bonsen, et al			
	4,113,853	09/12/78	Funakoshi, et al			
	4,650,786	03/18/87	Wong		-	
	4,857,636	08/15/89	Hsia			

EXAMINER	DATE CONSIDERED

Sheet 4 of 8

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.	Serial No.	
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	02-1076-A	10/767,516	
	(Use several sheets if necessary)			
		Applicant:		
		Avella, et al		
		Filing Date:	Group:	
		January 29, 2004		

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	5,028,588	07/02/1991	Hoffman, et al			
	4,001,200	01/04/1977	Bonsen, et al			
	4,061,736	12/06/1977	Morris, et al			
	4,136,093	01/23/1979	Bonhard, et al			
	4,526,715	07/02/1985	Koke, et al			
	4,529,719	07/16/1985	Туе			
	5,691,453	11/25/1997	Wertz			
	4,711,852	12/08/1987	Jacobson, et al			
	4,761,209	08/02/1988	Bonaventure, et al			
	4,835,097	05/30/1989	Saunders			

EXAMINER	DATE CONSIDERED

Sheet 5 of 8

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.	Serial No.
INFORMAT STATEMEI	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		10/767,516
(Coo Soveral Sheets II Nesessaly)		Applicant:	
		Avella, et al	
		Filing Date:	Group:
		January 29, 2004	

U.S. PATENT PUBLICATIONS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	2002/0065211	05/30/02	Jacobs, Jr., et al			
				į		

FOREIGN PATENT DOCUMENTS

					Translation
Document Number	Date	Country	Class	Subclass	
WO 00/21366	20 April 2000	PCT			YES
WO 97/35883	2 October 1997	PCT			YES
EP 0 361 720 A	4 April 1990	EP			No

EXAMINER	DATE CONSIDERED

Sheet 6 of 8

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Comm		Atty. Docket No.	Serial No.
(NGV. 2-32)	Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT	02-1076-A	10/767,516	
	(Use several sheets if necessary)			
			Applicant:	
			Avella, et al	_
			Filing Date:	Group:
			January 29, 2004	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

Gould, S.A., et al., The Life-Sustaining Capacity of Human Polymerized Hemoglobin when Red Cells Might Be Unavailable, Journal of the American College of Surgeons, 195 (4):445-455 (October, 2002).
Carson, J.L., et al., Mortality and morbidity in patients with very low postoperative Hb levels who decline blood transfusion, Transfusion, 42: 812-818 (July, 2002).
Moore, F.A., et al., Trauma Resuscitation, ACS Surgery- Principles & Practice, 31-61 (2002).
American College of Surgeons Committee on Trauma. Advanced Trauma Life Support Program for Physicians 1997 Instructional Manual, 6 th , ed. Chicago: American College of Surgeons; 98-117 (1997).
Farion, K.J., et al., Changes in Red Cell Transfusion Practice among Adult Trauma Victims, J. Trauma, 44(4):583-587 (1998).
Baker, J.B., et al., Type and Crossmatch of the Trauma Patient, J. Trauma, 50(5):878-881(May, 2001).
DeFoe, G.R., et al., Lowest Hernatocrit on Bypass and Adverse Outcomes Associated with Coronary Artery Bypass Grafting, Ann Thorac Surg., 71:769-776 (2001).
Wu, W.C., et al., Blood Transfusion in Elderly Patients with Acute Myocardial Infarction, New England Journal of Medicine, 345(17):1230-1236 (October, 2001).
Practice Guidelines for Blood Component Therapy: A report by the American Society of Anesthesiologists Task Force on Blood Component Therapy, Anesthesiology 84(3):732-747 (March, 1996).
Consensus Conference. Perioperative Red Blood Cell Transfusion, JAMA 260(18): 2700-2703 (November, 1988)
Gould, S.A., et al., Fluosol DA-20 As A Red Cell Substitute in Acute Anemia, New England Journal of Medicine, 314(26):1653-1656 (June, 1986).
Spence, R.K., et al., Fluosol DA-20 in the treatment of severe anemia: Randomized, controlled study of 46 patients, Critical Care Medicine, 18(11):1227-1230 (November, 1990).
Spence, R.K., et al., Is Hemoglobin Level Alone a Reliable Predictor of Outcome in the Severely Anemic Patient? The American Surgeon, 58(2):92-95 (1992).
Carson, J.L, et al., Severity of Anaemia and Operative Mortality and Morbidity, Lancet 1(8588):727-729 (April, 1988).

EXAMINER	DATE CONSIDERED

Sheet 7 of 8

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce	Atty. Docket No.	Serial No.
(NGV. 2-32)	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	02-1076-A	10/767,516
(Use several sheets if necessary)		Applicant:	
		Aveila, et al	
		Filing Date:	Group:
		January 29, 2004	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

Carson, J.L., et al., Effect of anaemia and cardiovascular disease on surgical mortality and morbidity, Lancet, 348(9034):1055-1060 (October, 1996).
Viele, M.K., et al., What can we learn about the need for transfusion from patients who refuse blood? The experience with Jehovah's Witnesses, Transfusion 34(5):396-401 (1994).
Sehgal L.R., et al., Polymerized pyridoxylated hemoglobin: A red cell substitute with normal oxygen capacity, Surgery 95:433-438 (1984).
Amberson, W.R., et al., Clinical Experience with Hemoglobin-Saline Solutions, J. Applied Physiology, 1(7):469-489 (January, 1949).
Brandt, J.L., et al., The Effects of Hemoglobin Solutions on Renal Functions in Man, Blood, 6:1152-1158 (1951).
Miller, J.H., et al., The Effect of Hemoglobin on Renal Function in The Human, Journal of Clinical Investigation, 30:1033-1040 (July, 1951).
Savitsky, J.P., et al., A clinical trial of stroma-free hemoglobin, Clinical Phamacology Journal, 23(1):73-80 (January, 1978).
Carmichael, F.J., et al., A phase I study of oxidized raffinose cross-linked human hemoglobin, Crit Care Med, 28(7):2283-2292 (2000).
Kasper, S.M., et al., Effects of a Hemoglobin-Based Oxygen Carrier (HBOC-201) on Hemodynamics and Oxygen Transport in Patients Undergoing Preoperative Hemodiulution for Elective Abdominal Aortic Surgery, Anesth Analg, 83:921-927 (1996).
LaMuraglia, G.M., et al., The reduction of the allogenic transfusion requirement in aortic surgery with a hemoglobin-based solution, J. Vascular Surgery, 31(2):299-308 (February, 2000).
Sloan, E.P., et al., Diaspirin Cross-Linked Hemoglobin (DCLHb) in the Treatment of Severe Traumatic Hemorrhagic Shock, JAMA 282:1857-1864 (November, 1999).
Gould, S.A., et al., Clinical Utility of Human Polymerized Hemoglobin as a Blood Substitute afterAcute Ttrauma and Urgent Surgery, J. Trauma 43(2):325-332 (August, 1997).
Gould, S.A., et al., The First Randomized Trial of Human Polymerized Hemoglobin as a Blood Substitute in Acute Trauma and Emergent Surgery, J Am Coll Surg 187(2):113-122 (August, 1998).
Vengelen-Tyler, V., American Association of Blood Banks Technical Manual. 13 th ed., Bethesda (MD): American Association of Blood Banks, p. 389-396 (1999).

EXAMINER	DATE CONSIDERED

Sheet 8 of 8

FORM PTO-1449 (Rev. 2-32)	Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Atty. Docket No.	Serial No.
(1.00. 2.02)		02-1076-A	10/767,516
(Use several sheets if necessary)			
		Applicant:	
		Avella, et al	
		Filing Date:	Group:
		January 29, 2004	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

Huston, P., et al., Withholding Proven Treatment in Clinical Research, New England Journal of Medicine 345(12):912-914 (September, 2001).
Emanuel, E.J., et al., The Ethics of Placebo-Controlled Trials- A Middle Ground, New England Journal of Medicine, 345(12):915-914 (September, 2001).
Carson, J.L, et al., Mortality and morbidity in patients with very low blood counts who decline blood transfusion, Transfusion, 42:812-818 (July, 2002).
Reiner, A.P., Massive Transfusion, Perioperative Transfusion Medicine, p.351-364 (1998).
Weiskopf, R.B., et al., Human Cardiovascular and Metabolic Response to Acute, Severe Isovolemic anemia, JAMA 279(3): 217-221 (January, 1998).
Wilkerson, D.K., et al., Limits of cardiac compensation in anemic baboons, Surgery, 103(6):665-670 (1988).
Levy, P.S., et al., Oxygen Extraction Ratio: A Valid Indicator of Transfusion Need in a Limited Coronary Vascular Reserve? J. Trauma 32(6):769-774 (June, 1992).
Schwartz, J.P., et al., The Influence of Coronary Stenosis On Transfusion Need., Cardiothoracic Surgery, Surgical Forum XLIV:226-228 (1993).
Moss, G.S., et al., Transport of Oxygen and Carbon Dioxide by Hemoglobin-Saline Solution in the Red Cell-Free Primate, Surg. Gynecol Obstet, 142:357-362 (March, 1976).
Frantantoni, J.C., Points to consider on efficiacy evaluation of hemoglobin and perfluorocarbon based oxygen carriers, Transfusion 34(8):712-713 (1994).
Frantantoni, J.C., Red Cell Subsitutes: Evolution of Approaches for Demonstrating Efficacy, Blood-substitutes – Present and Future Perspectives, Elsevier Science S.A., p. 33-39 (1998).
Sehgal, L.R. et al., <i>Preparation and in vitro characteristics of polymerized pyridoxylated hemoglobin</i> , Transfusion, 23(2):158-162 (1983).
Sharma, A., et al., An Isologous Porcine Promoter Permits High level Expression of Human Hemoglobin in Transgenic Swine, Biotechnology, 12:55-59 (1994).
Looker, D., et al., A human recombinant haemoglobin designed for use as a blood substitute, Nature, 356:258-260 (1992).

EXAMINER	DATE CONSIDERED